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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,777	10/03/2003	Michael G. Tovey	TOVEY-5A	1014

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EXAMINER	
GARVEY, TARA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/677,777	**Applicant(s)** TOVEY ET AL.	
	Examiner Tara L. Garvey	**Art Unit** 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-69* is/are pending in the application.

4a) Of the above claim(s) *35-69* is/are withdrawn from consideration.

5)☒ Claim(s) *34* is/are allowed.

6)☒ Claim(s) *12-15 and 17-33* is/are rejected.

7)☒ Claim(s) *2-11 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/3/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-69 are pending. Receipt of an amendment filed on January 23, 2006 is acknowledged.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-34) in the reply filed on January 23, 2006 is acknowledged.

Claims 35-69 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 23, 2006.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 12, 21, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Harpold et al (US 5,436,128; cited in the IDS submitted on October 3, 2003).

Harpold et al teach a recombinant cell that expresses a cell surface receptor and contains a construct that included s reporter gene, a promoter and other transcriptional regulatory sequences. The promoter and/or the transcriptional regulatory sequences are responsive to intracellular signals that are a result of the interaction between the cell surface protein and an extracellular signal. One example of a cell type utilized is Ltk, which is mammalian. The reporter gene can be a gene that encodes chloramphenicol acetyltransferase, firefly luciferase, bacterial luciferase, β-galactosidase or alkaline phophatase. One example demonstrates that the recombinant cell is treated with an agonist, incubated at 37°C for 5 hours and then assayed for the CAT reporter gene activity (abstract, column 7, lines 54-67, column 8, lines 1-2 and 35-41, column 10, line 59 bridging column 11, column 11, line 50 to column 13, column 14, lines 11-50, column 24, lines 30-54). The cell described by Harpold et al reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression. Thus, Harpold et al teaches all that is recited in the instant claims.

Claims 1, 12-14, 19, 21, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Canosi et al (Journal of Immunological Methods (1996) volume 199, pages 69-76; cited in the IDS submitted on October 3, 2003).

Canosi et al teaches a monkey Vero cell that contains pMx-Luc, which is a plasmid that expresses the luciferase gene under the control of the type I IFN mouse Mx1 promoter. Canosi et al further teaches that the cell is treated with the cytokine IFN-β at 37°C for 21 hours, which activates the promoter produce the reporter gene product. This assay is performed in a 96-well format, which reads on a microtiter plate (abstract, page 69, right column bridging page 70, page 71, left column, second full paragraph bridging right column and page 75). The cell described by Canosi et al reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression. Thus, Canosi et al teaches all that is recited in the instant claims.

Claims 1, 12-14, 17, 19, 21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lewis, JA (Journal of Immunological Methods (1995) volume 185, pages 9-17; cited in the IDS submitted on October 3, 2003).

Lewis teaches a cell that contains a reporter gene linked to an interferon-responsive promoter element and the reporter gene product is produced upon exposure of the cell to interferon. Lewis teaches a Ltk cell that contains a reporter construct that includes a GBP promoter is operably linked to a bacterial CAT reporter gene. The GBP promoter responds to signaling initiated by treatment of the cell with IFN-γ for 24 to 48 hours in a 96-well format (i.e. microititer assay). The GBP promoter is able to respond to both type I and type II interferons (abstract, page 10, left column, first full paragraph to right column, pages 12-13, page 14, right column, page 15, left column, last paragraph bridging right column and page 16, right column). The cell described by Lewis reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression. Thus, Lewis teaches all that is recited in the instant claims.

Claims 1, 12-15, 19, 21, 22 and 25-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Lallemand et al (Journal of Leukocyte Biology (1996) volume 60, pages 137-146; cited in the IDS submitted on October 3, 2003).

Lallemand et al teaches a human promonocytic U937 cell that contains a construct that contains a reporter plasmid with an ISRE-SV40 promoter-luciferase. This cell reads on a PIL5 cell. The cell was incubated with samples to be tested for interferon content for 12 hours at 37°C and the reporter gene was expressed in response to IFN-induced signal transduction (abstract, page 138, left column, last paragraph to right column and page 145, left column second paragraph). The cell described by Lallemand et al reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression. Thus, Lallemand et al teaches all that is recited in the instant claims.

Claims 1, 12, 13, 17-19, 21-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamb et al (US 5,707,803).

Lamb et al teaches a cell that contains a luciferase reporter gene under the control of a GAS element that is bound by transcriptional regulatory in response to a signaling molecule such as a cytokine. Furthermore, the cells were treated with IFN-γ, which reads on a type II interferon and the cells were harvested 5 hours later to measure the luciferase activity. The treatment with IFN-γ resulted in an increase in luciferase expression. Additionally, the reporter gene can encompass other genes such as CAT, β-gal or green fluorescent protein (GFP) (abstract, column4, lines 29-26, column 5, lines 7-10 and 59-67, column 6, lines 1-5, column 8, lines 45-55 and 63-67, column 9, lines 1-7 and column 19, lines 10-48). The cell described by Lamb et al reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression. Thus, Lamb et al teaches all that is recited in the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 12, 21, 22, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harpold et al (US 5,436,128; cited in the IDS submitted on October 3,

2003) in view of Button et al (Cell Calcium (1993 October), volume 14(9), pages 666-671; abstract).

Harpold et al teach a recombinant cell that expresses a cell surface receptor and contains a construct that included s reporter gene, a promoter and other transcriptional regulatory sequences. The promoter and/or the transcriptional regulatory sequences are responsive to intracellular signals that are a result of the interaction between the cell surface protein and an extracellular signal. One example of a cell type utilized is Ltk, which is mammalian. The reporter gene can be a gene that encodes chloramphenicol acetyltransferase, firefly luciferase, bacterial luciferase, β-galactosidase or alkaline phophatase. One example demonstrates that the recombinant cell is treated with an agonist, incubated at 37°C for 5 hours and then assayed for the CAT reporter gene activity (abstract, column 7, lines 54-67, column 8, lines 1-2 and 35-41, column 10, line 59 bridging column 11, column 11, line 50 to column 13, column 14, lines 11-50, column 24, lines 30-54).

Harpold et al do not teach using aequorin as the reporter for determining the level of Ca2+ in response to cell surface protein activation by a ligand.

Button et al teach a mammalian cell that stably expresses aequorin and is used to determine the activation of Ca2+ mobilization by cell-surface receptors. The cell is exposed to ligands that activate cell surface receptors coupled to increases in intracellular Ca2+ (abstract).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Harpold et al to use aequorin as the reporter gene because Harpold et al teach that it is within the ordinary skill in the art to have a recombinant cell that expresses a reporter gene in response to signaling activated by a cell surface protein and because Button et al demonstrate that aequorin can be used as a reporter of Ca2+ activation by receptor induced signaling pathway. One would have been motivated to do so in order to receive the expected benefit, as suggested by Button et al of screening ligands for their ability to activate a cell surface receptor that increases the level of intracellular Ca2+ in a cell. Absent of any evidence to the contrary, there would have been reasonable expectation of success in using the aequorin reporter gene taught by Button et al in the recombinant cell taught by Harpold et al.

Claims 1, 12-15, 17-23 and 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, JA (Journal of Immunological Methods (1995) volume 185, pages 9-17; cited in the IDS submitted on October 3, 2003) in view of Lallemand et al (Journal of Leukocyte Biology (1996) volume 60, pages 137-146; cited in the IDS submitted on October 3, 2003) and Lamb et al (US 5,707,803).

Lewis teaches a cell that contains a reporter gene linked to an interferon-responsive promoter element and the reporter gene product is produced upon exposure of the cell to interferon. Lewis teaches a Ltk cell that contains a reporter construct that includes a GBP promoter is operably linked to a bacterial CAT reporter gene. The GBP promoter responds to signaling initiated by treatment of the cell with IFN-γ for 24 to 48 hours in a 96-well format. The GBP promoter is able to respond to both type I and type II interferons (abstract, page 10, left column, first full paragraph to right column, pages

12-13, page 14, right column, page 15, left column, last paragraph bridging right column and page 16, right column). The cell described by Lewis reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression.

Lewis does not specifically teach that the promoter comprises both ISRE and GAS elements for induction of signalling by type I interferon and/or type II interferon.

Lallemand et al has been described previously. In particular, Lallemand et al teaches a cell containing a reporter construct under the control of an ISRE for detection of type I interferon signaling (abstract, page 138, left column, last paragraph to right column and page 145, left column second paragraph).

Lamb et al has been described previously. In particular, Lamb et al teaches a cell containing a reporter construct under the control of GAS element for detection of type II interferon signaling (abstract, column4, lines 29-26, column 5, lines 7-10 and 59-67, column 6, lines 1-5, column 8, lines 45-55 and 63-67, column 9, lines 1-7 and column 19, lines 10-48).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Lewis et al to include both a an ISRE and a GAS transcriptionally regulatory element in the reporter construct because Lewis teaches that it is within the ordinary skill in the art to provide a recombinant cell that comprises a reporter gene under the control a promoter that is responsive to both type I and type II interferons and because Lallemand et al and Lamb et al demonstrate that that ISRE and GAS elements are responsive to type I and type II interferons respectively. One would have been motivated to do so in order to receive the expected benefit, as suggested by Lewis et al and actually exemplified by Lallemand et al and Lamb et al, of detecting the presence of type I and type II interferons in the same assay. Absent of any evidence to the contrary, there would have been reasonable expectation of success in modifying the recombinant cell of Lewis to include ISRE and GAS elements.

Claims 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis, JA (Journal of Immunological Methods (1995) volume 185, pages 9-17; cited in the IDS submitted on October 3, 2003) in view of Ahern, H (The Scientist (1995) volume 9, issue 15, pages 20-27).

Canosi et al teaches a monkey Vero cell that contains pMx-Luc, which is a plasmid that expresses the luciferase gene under the control of the type I IFN mouse Mx1 promoter. Canosi et al further teaches that the cell is treated with the cytokine IFN-β at 37°C for 21 hours, which activates the promoter produce the reporter gene product. This assay is performed in a 96-well format, which reads on a microtiter plate (abstract, page 69, right column bridging page 70, page 71, left column, second full paragraph bridging right column and page 75). The cell described by Canosi et al reads on a cell that maintains signal transduction activity for at least an hour because the cell is treated and cultured for several hours prior to analysis of the reporter gene expression.

Canosi et al does not teach that the cell is provided in a kit.

Ahern, H teaches that is an advantage to having a kit is that an investigator can simply by a kit rather than searching for all of the individual components of the assay and the kit even provides the investigator with instructions to follow. Ahern further states that "kits accelerate the research process" (page 23).

It would have been obvious to one of ordinary skill in the art to modify the teachings of Canosi et al to provide a kit comprising the reagents for detecting interferon levels that induce a signaling pathway because Canosi et al teaches that it is within the ordinary skill in the art to use a recombinant cell to determine the levels of IFN in a sample and because Ahern demonstrate that a kit provides an investigator with an efficient product for carrying out experiments. One would have been motivated to do so in order to receive the expected benefit, as suggested by Ahern of providing an easy, efficient and reproducible product to determine the amount of interferon in a sample. Absent of any evidence to the contrary, there would have been reasonable expectation of success in providing the reagents taught by Canosi et al in a kit.

Allowable Subject Matter

Claims 2-11 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 34 is allowed.

Conclusion

Claims 1, 12-33 are rejected. Claims 2-11 are objected. Claim 34 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-2917. The examiner can normally be reached on Monday through Friday 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Tara L Garvey, Ph.D.
Examiner
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